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I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Assistant Commissioner for Patents, Washington, D.C. 20231.

John M. Kilcoyne

Type or print name

John M. Kilwyne Signature

September 26, 2001 Date

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

Art Unit: 1615

TIMMINS ET AL.

Examiner: P. Kulkosky

APPLICATION NO: 09/398,107

FILED: SEPTEMBER 16, 1999

FOR: BIPHASIC CONTROLLED RELEASE DELIVERY SYSTEM FOR

HIGH SOLUBILITY PHARMACEUTICALS AND METHOD

Assistant Commissioner for Patents Washington, D.C. 20231

# INFORMATION DISCLOSURE STATEMENT

Sir:

This Information Disclosure Statement is being filed in accordance with 37 C.F.R. §1.97(c). A letter for payment of fee set forth in 37 C.F.R. §1.17(p) is enclosed.

In accordance with 37 C.F.R. §1.56, applicants wish to call the Examiner's attention to the documents cited on the attached form(s) PTO-1449.

Copies of these documents are enclosed herewith.

The Examiner is requested to consider the foregoing information in relation to this application and indicate that each document was considered by returning a copy of the initialed PTO 1449 form(s).

10/02/2001 MBERHE

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Respectfully submitted,

Bristol-Myers Squibb Company Patent Department P.O. Box 4000 Princeton, NJ 08543-4000

Date: September 26, 2001

John M. Kilcoyne Attorney for Applicants

Reg. No. 33,100 (609) 252-5909



**CERTIFICATE OF MAILING** 

I hereby certify that this paper (and AURINAL) paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Assistant Commissioner for Patents, Washington, D.C. 20231.

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Assistant Commissioner for Patents Washington, D.C. 20231

## FEE LETTER FOR INFORMATION DISCLOSURE STATEMENT

Sir:

Please charge Deposit Account No. 19-3880 in the name of Bristol-Myers Squibb Company in the amount of \$180 for payment of the fee pursuant to 37 CFR §1.17(p) for the submission of an Information Disclosure Statement under 37 CFR §1.97(c).

An additional copy of this paper is here enclosed. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Account No. 19-3880 in the name of Bristol-Myers Squibb Company.

Respectfully submitted,

Bristol-Myers Squibb Company Patent Department P.O. Box 4000 Princeton, NJ 08543-4000 (609) 252-5909

Date: September 26, 2001

John M. Kilcoyne Attorney for Applicants

Reg. No. 33,100

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# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

9/28/0

IN RE APPLICATION OF

Art Unit: 1615

TIMMINS ET AL.

Examiner: J. Spear

APPLICATION NO: 09/398,107 FILED: SEPTEMBER 16, 1999

FOR: BIPHASIC CONTROLLED RELEASE DELIVERY SYSTEM FOR

HIGH SOLUBILITY PHARMACEUTICALS AND METHOD

Assistant Commissioner for Patents Washington, D.C. 20231



#### INFORMATION DISCLOSURE STATEMENT

Sir:

As requested, attached are copies of the Information Disclosure Statements dated July 14, 1998, and September 16, 1999, already submitted in this application.

Also attached is an Information Disclosure Statement listing

- (i) U.S. Patent No. 6,340,475 (recently issued on January 22, 2002) andU.S. 2001/0018070 (published August 30, 2001) which are both in the patent family for WO 98/55107 which was already cited herein, and
- (ii) U.S. Patent No. 5,955,106 (issued September 21, 1999) which is in the patent family for ZA 957670 also already cited herein.



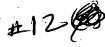
The Examiner is requested to consider the foregoing information in relation to this application and indicate that each document was considered by returning a copy of the initialed PTO 1449 form(s).

Respectfully submitted,

Bristol-Myers Squibb Company Patent Department P.O. Box 4000 Princeton, NJ 08543-4000 (609) 252-5909

Date: March 21, 2002

John M. Kilcoyne
Attorney for Applicants
Reg. No. 33,100



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Patent Case No. LA23b

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Peter Timmins et al

Filed: For:

Herewith BIPHASIC CONTROLLED RELEASE DELIVERY SYSTEM FOR

HIGH SOLUBILITY PHARMACEUTICALS AND METHOD

Princeton, New Jersey 08543 7000 September 16, 1999

#### INFORMATION DISCLOSURE STATEMENT

To the Commissioner of Patents and Trademarks:

This information disclosure statement is being presented as a means of complying with the requirements of 37 CFR 1.56. It includes what the undersigned believes to be the closest prior art. However, no representation is made that better art does not exist nor that a search has been made.

Copies of references were provided in previous patent application Serial No. 09/044,446 filed 03/19/98 (copies of Information Disclosure Statement and Form PTO-1449 are attached), and the following reference was cited by the Examiner, WO 96/08243 PCT (South African counterpart Patent Application No. 95/7670 is enclosed)

Copies of the following additional references are enclosed: Noel, M., "Kinetic study of normal and sustained release dosage forms of metformin in normal subjecs"; and Karttunen, P. et al., "The pharmacokinetics of metformin: a comparison of the properties of a rapid-release and a sustained-release preparation".

Respectfully submitted,

Burton Rodney Attorney

BR:mz Enclosures (609) 252-4336